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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SNYDER, STUART

ART UNIT	PAPER NUMBER
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1648

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/581,371	Applicant(s) GROVES ET AL.	
	Examiner STUART W. SNYDER	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/31/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1-37 are pending in the present Application; claims 1-17 are withdrawn as being drawn to a non-elected invention. Acknowledgement is made of amendment of claim 18 and addition of claims 33-37. Claims 18-37 are examined herein.

Comments/Art Rejection

2. All previous art rejections are **withdrawn** in view of amendment of claim 18.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 18, 25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Linnecke and Wong, US 4240751. The claims are drawn to an assay system for detecting an analyte comprising a suspension of colloidal particles associated with more than one copy of a ligand specific for an analyte and a device for detecting a phase transition from a first phase to a second phase when contacted with a second analyte. Further limitations of the claims include that the limitation that the ligand is non-covalently linked to the colloidal particles (claim 25) and that the first phase is a dispersed phase and the second phase is a condensed phase.

Linnecke and Wong teaches a so-called latex agglutination assay in which ligands for a desired analyte are non-covalently bound to a latex bead. Upon binding to the analyte, the latex beads condense and the condensed phase is detected spectrometrically; see, for example, paragraphs 92-96. Thus, each and every limitation of the claims is taught by Linnecke and Wong.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 19-21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Linnecke and Wong as applied to claims 18, 25, and 27 in view of Singh, *et al.* The limitations of claim 18 are summarized above (see section 6); claims 19-21 and 30 add the following limitations to the independent claims: The colloidal suspension comprises two independent particle populations (claim 19) which are distinguishable by size (claim 20) or by differential labeling of the particles (claim 21). Singh, *et al.* teach methods and materials for separation and analysis of complex materials including biological materials. Separation and analysis depends on use of differentially labeled nanoparticles used to capture desired analytes and to distinguish the various populations of analyte/nanoparticles. Distinguishing characteristics of the nanoparticles include size and composition of the

Art Unit: 1648

nanoparticles; the latter aspect may be distinctive fluorescence profiles. Thus, Singh, *et al.* teaches each and every limitation of claims 19-21 and 30.

It would have been obvious for a skilled artisan to use at least two populations of nanoparticles in diagnostic compositions. The skilled artisan would be motivated to use at least two populations of nanoparticles to analyze complex biological compositions comprising two or more analytes of interest (see Singh, *et al.*, abstract and introduction) whilst minimizing sample size or other analytical resources. The skilled artisan would have reasonable expectation of success because of the wide spread use of multiplex technology comprising nanoparticles especially in the flow cytometric arts. Thus, the invention of claims 19-21 is *prima facie* obvious in view of Linnecke and Wong and Singh, *et al.*

5. Claims 22-24, 28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Linnecke and Wong in view of Schaertl, *et al.* (J Biomol Screen, 2001). The limitations of claim 18 is summarized above; the instantly rejected claims add the following limitations: the colloidal particles comprise a lipid layer (claims 22, 28, and 36); the lipid layer further comprises a natural cell membrane (claim 23 and claim 31); the colloidal particles are covalently linked to the specific ligand of the colloidal particles (claim 24) and the lipid-coated particle is non-covalently linked to the particle.

The teachings of Linnecke and Wong are summarized above (see section 5, above). Schaertl, *et al.* teaches use of nanoparticles labeled with antibodies or other specific binding partners in an ELISA type assay (see, for example, Fig. 1,

Art Unit: 1648

page 228). One of the species of nanoparticles used was non-replicating *E. coli* which inherently possesses a natural lipid bi-layer capable of presenting the capture agent to liquid phase. A second format taught by Schaertl, *et al.* is a synthetic nanoparticle to which binding agents are covalently attached to the nanoparticle. Furthermore, as with the assay of the instant Application, the assay of Schaertl, *et al.* can be performed in a homogeneous format.

It would have been obvious to use the nanoparticles of Schaertl, *et al.* in the assay of Linnecke and Wong to increase the range of analytes available for detection. A skilled artisan would have been motivated to use *E. coli* or synthetic nanoparticles as a nanoparticle in Linnecke and Wong's assay because of the common desire of both groups to specifically detect analytes, especially those in low concentrations. Said skilled artisan would have a reasonable expectation of success, especially when expressing antibody-like molecules on the surface of the bacteria or attaching them to nanoparticles, because clumping of either nanoparticle would occur because of the multivalent nature of the particles. Thus, the invention of claims 22-24 and 31 are *prima facie* obvious and the claims are properly rejected under 35 U.S.C. 103(a) as being unpatentable over Linnecke and Wong in view of Schaertl, *et al.*

6. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Linnecke and Wong. Claim 26 is drawn to a composition for detecting pre-specified analytes comprising nanoparticles that undergo phase transition in the presence of the analytes comprising transition of a condensed phase to a

Art Unit: 1648

dispersed phase. As explained above, Linnecke and Wong teaches phase transition of a dispersed phase to a condensed phase. However, it is very well known and long practiced in the analytical arts to utilize so-called competitive binding assays to kinetically characterize analytes. In such assays, the skilled artisan may employ the same capture probe (specific to the analyte) in both solid and solution phase to determine affinity constants or, in other formats, a non-identical inhibitor of capture probe-analyte binding.

It would have been obvious for a skilled artisan to utilize the composition of Linnecke and Wong in a competitive format to arrive at a system that detects pre-selected analytes by monitoring a phase transition from condensed phase to dispersed phase. The skilled artisan would have been motivated to further characterize detected analytes kinetically or to determine/discover inhibitory entities. The skilled artisan would have a reasonable expectation of success because of the ubiquity and success of competitive methodology. Thus, the invention of claim 26 are *prima facie* obvious and the claims are properly rejected under 35 U.S.C. 103(a) as being unpatentable over Linnecke and Wong

7. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Linnecke and Wong in view of Faulds, *et al.* Claim 29 adds the limitation that the means for detecting comprises a microscope. Faulds, *et al.* teaches using a microscope for detecting Raman scattering of light from amphetamine sulfate adsorbed to colloidal surfaces (see page 283).

Art Unit: 1648

It would have been obvious to use a microscope in the method of Linnecke and Wong because of the common desire of each investigative group to detect analytes using colloidal suspensions to adsorb the analytes and subsequently detect a physical change of the colloids. A skilled artisan would have reasonable expectation of success in using a microscope in Linnecke and Wong's method because of the ease of viewing clusters of colloidal particles. Thus, each and every limitation of claim 29 is taught by the combination of Linnecke and Wong, *et al.* and Faulds, *et al.*; the invention of claim 29 is therefore *prima facie* obvious over Linnecke and Wong, *et al.* and Faulds, *et al.* and properly rejected under 35 U.S.C. 103(a).

8. Claims 33-35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Linnecke and Wong in view of Strauss (US 4410660). Claims 33-35 and 37 are drawn to the assay of claims 18 or 28 with the further limitation that the microparticles are either silica or metal microparticles. Linnecke and Wong do not teach such microparticles. Strauss teaches detection of Mycobacteria using latex particles but suggests that such particles may easily be replaced by other types of microparticles including silica or metal particles (see para. 35).

It would have been obvious to use silica or metal microparticles in the method of Linnecke and Wong because of the common desire of each investigative group to detect analytes using colloidal suspensions to adsorb the analytes and subsequently detect a physical change of the colloids. A skilled artisan would have reasonable expectation of success in using silica or metal microparticles in

Art Unit: 1648

Linnecke and Wong's method because of the interchangeability of such particles, as taught by Strauss. Thus, each and every limitation of claims 33-35 and 37 is taught by the combination of Linnecke and Wong, *et al.* and Strauss; the invention of claims 33-35 and 37 is therefore *prima facie* obvious over Linnecke and Wong, *et al.* and Strauss and properly rejected under 35 U.S.C. 103(a).

Conclusion

9. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1648

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART W. SNYDER whose telephone number is (571)272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick J. Nolan can be reached on (571) 272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/
Primary Examiner, Art Unit 1648

Stuart W Snyder
Examiner
Art Unit 1648

SWS